Rev.5

DECLARATION OF CONFORMITY

We, TERUMO CORPORATION
44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan

being the manufacturer of :

RADIFOCUS Optitorque
Angiographic Catheter

Product : Angiographic Catheter (GMDN 10688)

declare that the above products of **Class III** are in conformity with the provisions of Annex I and Annex II of the EC Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, and have been subject to the following conformity assessment procedure laid down in the EC Council Directive 93/42/EEC Article 11, 1(a) relating to the "Full quality assurance" set out in Annex II, under the supervision of TÜV Rheinland (Registration No.: HD 60012340 0001 ID 60016784 0001), as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

Authorized European Representative :
TERUMO EUROPE N.V.
Researchpark Zone 2 Haasrode, Interleuvenlaan 40
3001 Leuven, Belgium

Tokyo, January 4, 2007
(place and date of issue)

A. Oguma

Akira Oguma
Director, General Manager
Quality Assurance Department
TERUMO CORPORATION

TERUMO®